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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,452	07/11/2003	Shelley D. Minteer	SLU 4554.1	4859
321	7590	12/10/2007	EXAMINER	
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			MARTIN, ANGELA J	
			ART UNIT	PAPER NUMBER
			1795	
			NOTIFICATION DATE	DELIVERY MODE
			12/10/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/617,452	<b>Applicant(s)</b> MINTEER ET AL.	
	<b>Examiner</b> Angela J. Martin	<b>Art Unit</b> 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-77 and 113-140 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 7, 9, 11, 27-41, 45, 48-77 and 113-140 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 8, 10, 12-26, 42-44, 46, 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

This Office Action is responsive to the Remarks to the Final Rejection, filed on November 20, 2007. The Applicant submitted a Declaration under 37 CFR 1.132. Applicant's arguments have been fully considered and are persuasive. Thus, a new rejection is presented for the following reasons of record.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 6, 8, 10, 12-26, 42-44, 46, 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15, 22, 40-44, and 48 of copending Application No. 10/931,147. Although the conflicting claims are not identical, they are not patentably distinct from each other because

although the instant claims are drawn to a bioanode, and the copending claims are drawn to a biocathode, it is noted that an electrode can be used as a bioanode or a biocathode or both, in a bio fuel cell, depending on whether it is to yield or gain electrons.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 12 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claim 12, the phrase "modified perfluoro sulfonic acid-PTFE copolymer" renders the claim indefinite because it is unclear what the modification is. Regarding claim 17, the phrase "modified with a hydrophobic cation larger than  $\text{NH}_4^+$ " renders the claim indefinite because it is unclear what the modification is.

- 6.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 8, 10, 12, 42-44, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karyakin et. al., Anal. Chem.

Karyakin discloses an electrode comprising glassy carbon electrodes (pg 4337) coated with Nafion (enzyme immobilization material) (perfluoro sulfonic acid-PTFE copolymer) and poly(methylene green) (electrocatalyst). The enzyme-Nafion complex was made by mixing the enzyme suspension with Nafion solution and by syringing an appropriate amount of the enzyme polyelectrolyte complex to the target surface and allowing the solvent to evaporate. The Examiner notes that the cocasting of Nafion and the enzyme allows for stabilization of the enzymes.

Karyakin discloses a bioelectrode, but does not expressly disclose that it is a biocathode. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Karyakin's electrode as either a biocathode or a bioanode or both in a bio fuel cell depending on if it were to yield or gain electrons. Being an anode, it necessarily is capable of yielding electrons to the electron conductor to produce an oxidized form of the electrocatalyst that is capable of reacting with an reduced form of the electron mediator to produce a oxidized form of the electron mediator and an reduced form of the electrocatalyst.

Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karyakin et. al., Anal. Chem, further in view of Jin, Mikrochim. Acta.

Karyakin teaches the bioanode as described above.

Karyakin does not teach Nafion® modified with quaternary ammonium cation.

Jin teaches an electrode modified with Nafion and methyl viologen with immobilized urate oxidase. Jin teaches that catalytic reduction of dissolved oxygen on the Nafion-methyl viologen electrode results in fast and sensitive dissolved oxygen determination (pg 71 and 74). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Nafion of Karyakin with methyl viologen for the benefit of fast and sensitive dissolved oxygen determination.

Claims 6, 13-16, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zawodzinski et. al., Electroanalysis, in view of Gregg (US 5264105).

Zawodzinski discloses an electrode comprising Nafion (electron conducting enzyme immobilization material), glucose oxidase (enzyme), and carbon supported platinum (abstract). The conductive substance can be either carbon glass or carbon paper (abstract). Zawodzinski discloses that the electrode responds rapidly and is stable over a long period (90% activity after more than half a year) (abstract).

Zawodzinski discloses a bioelectrode, but does not expressly disclose that it is a biocathode. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Zawodzinski's electrode as either a biocathode or a bioanode or both in a bio fuel cell depending on if it were to yield or gain electrons. Being a cathode, it necessarily is capable of gaining electrons from the electron conductor to produce a reduced form of the electrocatalyst that is capable of reacting with an oxidized form of the electron mediator to produce a reduced form of the electron mediator and an oxidized form of the electrocatalyst.

Zawodzinski discloses platinum as catalyst, but it is noted that it is not capable of gaining electrons from the electron conductor.

Gregg teaches a redox compound, or redox centers. Transition metal complexes with organic ligands such as bipyridine are preferred as redox centers because of their chemical stability and various oxidation states and their fast electron transfer kinetics. Examples of such complexes include polypyridine complexes of di- or trivalent osmium ions. The term "redox compound" is used herein to mean a compound that can be oxidized and reduced. The redox compound may have one or more functions that are reducible and oxidizable. Further, the term "redox compound" means a compound which contains one or more redox centers, "redox center" meaning a chemical function that accepts and transfers electrons (3:33-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Zawodzinski's platinum with Gregg's

osmium<sup>2+</sup>(2,2'bipyridine)<sub>3</sub> for the benefit of providing fast chemical reaction of the analyte material.

Gregg discloses that in Example 2 that the concentration of osmium bis bipyridine chloride is 456 mg/100 ml EtOH, or 0.01 M ( 7: 65). The calculation is based on the molecular weight of osmium bis bipyridine chloride as 444 g/mol.

Gregg does not disclose the concentration as claimed in claims 34-37.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the concentration of the transition metal complex to meet the electron transfer kinetics of the electrode. It has been held by the courts that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Swain et al.*, 33 CCPA 1250, 156 F.2d 239, 70 USPQ 412.

Claims 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zawodzinski et. al., Electroanalysis, in view of Gregg (US 5264105), and further in view of Khan (US 2004/0217016).

Zawodzinski modified by Gregg teaches all the elements of claim 6 and is incorporated herein. Zawodzinski discloses that the redox enzyme is glucose oxidase and does not disclose that the redox enzyme is bilirubin oxidase.



However, Khan discloses that the specific enzyme present depends on the particular analyte for which the electrochemical test is designed to detect, which includes bilirubin oxidase [0029].

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use bilirubin oxidase should the analyte be bilirubin, as bilirubin oxidase is capable of oxidizing bilirubin when used as the analyte. In this case, Khan's teaching of selecting a specific enzyme in the reaction area depending on the particular analyte demonstrates that compatibility is required when choosing enzyme-analyte systems. As such, it is contended that they both are fully compatible.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela J. Martin whose telephone number is 571-272-1288. The examiner can normally be reached on Monday-Friday from 10:00 am to 6:00 pm.

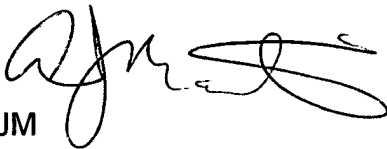
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Ryan can be reached on 571-272-1292. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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AJM

A handwritten signature in black ink, appearing to be 'AJM' followed by a stylized flourish.